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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,648	04/13/2000	Zeling Cai	ORT1224	6532

7590 10/25/2004

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/548,648

Applicant(s)

CAI ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/16/04 and 8/16/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 8/16/04 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks filed 6/16/04 have been entered.
2. Claims 1, 3, and 5-7 are pending and being acted upon.
3. In view of Applicant's amendments, all previous rejections have been withdrawn. In particular, the method as now claimed comprises an assay method which employs a recombinant cell expressing a labeled MHC class I component. This new limitation is not taught by the prior art wherein the assay methods employ an isolated MHC class I component.
4. The following are new grounds for rejection.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1, 3, and 5-7 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method for the detection of antigen specific T cells, comprising:

- a. providing a recombinant cell expressing an MHC class I protein-fluorescent protein fusion molecule or a radiolabeled MHC class I protein on a surface of the recombinant cell;

b. contacting the MHC class I protein-fluorescent protein fusion molecule or the radiolabeled MHC class I protein, bound to a specific antigen with a population of T cells;

c. incubating the fusion molecule or the radiolabeled MHC class I protein bound to the specific antigen together with the population of T cells for a period of time sufficient for the T cells to internalize the fusion molecule or the radiolabeled MHC class I protein from the T cell surface; and

d. identifying the T cells that have internalized the fusion molecule or the radiolabeled MHC class I protein (Claim 1).

Applicant's amendment, filed 6/16/04, asserts that support for the amendment can be found at page 5, lines 8-10 of the specification.

Page 5, lines 8-10 of the specification disclose, "L^d-GFP expressing cell lines were used as antigen presenting cells (APCs) to present specific QL9 peptide (7) to CD8⁺ T-cells from the 2C TCR transgenic-mouse line (2C T-cells), which specifically recognize the T-cell antigen QL9 (8)." It is unclear how this disclosure supports the method as now claimed.

A review of the application shows that the generic method of the original claims comprised a method for the purification of T cells comprising contacting T cells with an MHC class I protein associated with a specific antigen. The newly claimed limitation of part a) of Claim 1, providing a recombinant cell expressing an MHC class I protein-fluorescent protein fusion molecule or a radiolabeled MHC class I protein on a surface of the recombinant cell was not present in the original claims. Accordingly, support for the new limitation to the generic claim must be found in the specification.

A review of the specification reveals little generic disclosure of the invention. The specification consists generally of the same teachings as the newly submitted Huang et al. (1999) reference, i.e., specific experiments employing a specific cell type, specific recombinant MHC class I constructs, and a specific antigen. Such a disclosure is insufficient support for the generic method of the claims, i.e., a method employing any recombinant cell, any recombinant MHC class I construct, and any antigen.

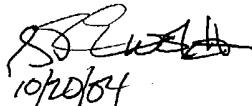
7. No claim is allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
Primary Examiner
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10/20/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER